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July 26, 2024

Honorable Sanket J. Bulsara, U.S.M.J.
United States District Court
Eastern District of New York
225 Cadman Plaza East
Brooklyn, NY 11201

Re: *Biofer S.p.A. v. Vifor (International) AG*, No. 1:22-cv-02180-AMD-SJB (E.D.N.Y.)

Dear Judge Bulsara:

Following the Court's March 29, 2024 Claim Construction Order (ECF 139), the parties have been discussing a potential stipulation of non-infringement in view of the Court's construction of the claim term "pH between 7.0 and 9.0." However, the parties have been unable to resolve an impasse over the meaning and import of that construction. As discussed herein, Biofer seeks clarification as to whether the Court's adoption of Defendant's construction of "pH between 7.0 and 9.0" to mean "pH is maintained in the interval separating 7.0 and 9.0" requires that the pH must be maintained *throughout* the recited step, as stated in the Court's Order and acknowledged by Vifor in prior correspondence. Vifor believes the Court's construction needs no further clarification. Nonetheless, Biofer believes this is a critical point in determining whether or not to proceed with the proposed stipulation, which would allow for an immediate appeal to the Federal Circuit and avoid unnecessary burdens and costs on the Court and parties during the pendency of the appeal. To be clear, the parties are not asking the Court to reconsider its construction. The parties also respectfully request that the deadline for the parties to submit a schedule be held in abeyance, pending the Court's decision on this letter.

Plaintiff Biofer's Position:

During claim construction, the parties' primary dispute over the term "pH between 7.0 and 9.0" involved "whether the claim encompasses only a process which occurs entirely at a pH between 7.0 and 9.0," (ECF 139 at 9-10), as Defendant Vifor argued in its briefing and at the *Markman* hearing (see, e.g., ECF 62 at e.g., 15 (Section "**2. pH Must be Maintained Throughout the Oxidation Reaction**"; ECF 73-1 at e.g., 3-5). The Court issued a Claim Construction Order (ECF 139) on March 29, 2024, adopting Defendants' construction, construing the term to mean "pH is maintained in the interval separating 7.0 and 9.0," and stating "that the intrinsic evidence supports that the pH range must be maintained throughout the process." *Id.* at 9-12.

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After the stay was lifted, Defendant sent a letter to Biofer on June 12, 2024 demanding that Plaintiff stipulate to non-infringement based on the Court's construction of this term, or face a claim for fees and costs should Biofer continue pursue what were described as "meritless claims" in view of the Court's construction. Ex. A. In its letter, Defendant asserted that "[t]he Court agreed with Vifor, adopt[ed] Vifor's proposed construction and conclude[d], '[a]ccordingly, the Court finds that the intrinsic evidence supports that **the pH range must be maintained throughout the process.**'" *Id.* at 1 (quoting ECF 139 at 12) (emphasis in original). Despite these statements, however, Vifor has been unwilling to include language in the proposed stipulation of non-infringement that, under the Court's construction, the pH range must be maintained "throughout" the process. Following a meet and confer, during which Defendant suggested that Plaintiff seek clarification of the Court's claim construction, the parties elected to continue trying to work out the language of a stipulation. Those further efforts narrowed the issue to the disputed language in the first sentence of Paragraph 1 of the attached. (*See* attached Ex. B, with the redline rejection of Plaintiff's proposed language by Defendant.).

Based on the foregoing, Biofer respectfully requests clarification as to whether or not the Court's construction of "pH between 7.0 and 9.0" requires that the pH must be maintained **throughout** the recited step. Biofer does not seek, as Defendant claims, an "advisory opinion" on a "new infringement theory."¹ It simply seeks clarification of the Court's construction based on Defendant's assertion that this construction is case dispositive. To the extent the Court clarifies that to be the intended meaning and import of the construction, then Plaintiff is prepared to enter the attached stipulation with its proposed language and proceed to an immediate appeal. The requested clarification is within the discretion of the Court and warranted under these circumstances. The Court has the discretion and latitude to resolve questions of claim scope, particularly when the course of litigation brings a dispute into focus. *See GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1310 (Fed. Cir. 2014) (the parties' dispute has "evolve[d] to a point" where additional clarification is necessary).

Defendant Vifor's Position:

Biofer's contention that the Court's construction of the term "pH between 7.0 and 9.0" to mean "a pH maintained in the interval separating 7.0 and 9.0" is ambiguous is entirely premised on its desire to obtain an advisory opinion as to the propriety of its new infringement theory generated after the Court's claim construction. Vifor believes no clarification is necessary and that Biofer should either stipulate to non-infringement or proceed with the case.

During claim construction, Biofer argued the phrase "pH between 7.0 and 9.0" "should not be restricted to a reaction that is maintained exclusively within the claimed pH range, but construed to allow reactions occurring outside of the claimed pH range consistent with its plain and ordinary meaning." (ECF 67 at 3.) During the *Markman* hearing, Biofer further confirmed its position, arguing that the term "[b]etween says nothing about time," and there is "no restriction intrinsically on duration that you spend within that range[.]" (ECF 139 at 12; *Markman* Tr. at 26:24-25; 27:4-5.) In doing so, Biofer agreed that "if any time during the process it falls within this range, [even]

¹ At Defendant's request, Biofer submitted final infringement contentions showing that Vifor maintained pH within the recited range for approximately 90% of the reaction or more before Defendant demanded that Plaintiff stipulate to non-infringement.

for a millisecond,” Vifor infringes and this issue of infringement should be decided on “a different day.” (Markman Tr. at 13:6-19.) The Court considered Biofer’s arguments and rejected them, adopting Vifor’s construction.² (ECF 139 at 9-16.)

On April 4, 2024, a few days after the Court issued its *Markman* Order, Vifor provided multiple reasons why Biofer should stipulate to non-infringement. Ex. C. After Vifor requested Biofer’s stipulation of non-infringement, Biofer served supplement infringement contentions, on May 24, 2024, asserting that at some point within a 72-hour window during “storage,” and after oxidation has been completed, oxidation nonetheless occurs at a pH “between 7.0 and 9.0” as construed by the Court. Ex. A at 1. In short, Biofer now asserts that the “a pH maintained in the interval separating 7.0 and 9.0” limitation is met at some undefined time point within a 72-hour window Biofer selected that is unquestionably outside the oxidation process defined in Vifor’s DMF. *Id.* at 1-2. As such, Biofer is now making the same arguments, albeit under the guise of infringement, that were already rejected by the Court; namely, that “between says nothing about time” or any “restriction intrinsically on [the] duration you spend within that range.” (ECF 39 at 12.) Biofer’s continued assertion of arguments rejected by the Court prompted Vifor’s June 12, 2024 letter. (Ex. A at 2.)

Rather than seek clarification, Biofer actually seeks an advisory opinion from the Court as to whether its new infringement theory can pass muster under the Court’s claim construction and to obtain quotes it can later cite to the Federal Circuit on appeal. *See Young Advoc.s for Fair Educ. v. Cuomo*, 359 F.Supp.3d 215, 229 (E.D.N.Y. 2019) (“From the earliest days of the Republic it has been recognized that [courts are] without power to give advisory opinions.”) (internal quotes omitted) (citation omitted); *Bellefonte Reinsurance Co. v. Aetna Cas. And Sur. Co.*, 590 F.Supp. 187, 190 (S.D.N.Y. 1984) (“[f]ederal courts are precluded by Article III from rendering advisory opinions.”). Indeed, Biofer’s letter here makes clear that it “seeks clarification of the Court’s construction based on Defendant’s assertion that this construction is case dispositive,” meaning Biofer believes it can proceed with its infringement case, but will not until the Court “clarifies,” i.e., advises them, on whether they can do so.

Biofer has multiple options at its disposal: (1) Biofer could accept Vifor’s changes to the *joint* stipulation of non-infringement and proceed to appeal (Ex. B.); (2) Biofer could file its own *unilateral* stipulation of non-infringement, including any language it desires, and proceed to appeal; or (3) if Biofer believes it can prevail on infringement based on the Court’s claim construction, it can proceed accordingly. None of these options require further clarification from the Court and none provide an improper advisory opinion with respect to Biofer’s new infringement theory. As such, Vifor believes no additional clarification or response is needed from the Court regarding its claim construction Order.

² Later obtained discovery in this case, including Biofer’s statements to the European Patent Office as well as deposition testimony from named inventor Egidio Marchi, further confirm the correctness of the Court’s construction.

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Sincerely yours,

/s/ Jonathan D. Ball

Jonathan D. Ball

/s/ Sanya Sukduang

Sanya Sukduang

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Format changes	0
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